EXHIBIT "2"

Expert Report of Dr. Salmon, Ph.D., MPH

April 9, 2025
Expert Report of Daniel Salmon, Ph.D., MPH

Professional Experience

Dr. Salmon is a Professor of Global Disease Epidemiology and Control, Department of International Health, Johns Hopkins University Bloomberg School of Public Health. He also has a joint appointment in the Department of Health, Behavior and Society. Dr. Salmon serves as the Director of the Institute for Vaccine Safety at Johns Hopkins.

Dr. Salmon is broadly trained in vaccinology, with an emphasis in epidemiology, behavioral epidemiology, and health policy. Dr. Salmon received a Bachelor of Arts (BA) in Political Science with a minor in Psychology from Rutgers University in 1991. He received a Master of Public Health (MPH) from Emory University Rollins School of Public Health in 1996. Dr. Salmon received a Doctor of Philosophy (PhD) from Johns Hopkins University Bloomberg School of Public Health in 2003.

Dr. Salmon has held positions in government and academia. Dr. Salmon has worked for the Centers for Disease Control and Prevention as a contractor and later as a Policy Analyst. In these positions, he used surveillance systems to conduct studies of measles and pertussis and coordinated Federal efforts around vaccine safety, immunization information systems, and development of new vaccines such as for tuberculosis. Dr. Salmon also served as the Director of Vaccine Safety, National Vaccine Program Office, Department of Health and Human Services. In this capacity, Dr. Salmon was responsible for coordinating and overseeing the nation's vaccine safety system including vaccine safety activities in the Department of Health and Human Services (National Institute of Health, Food and Drug Administration, Centers for Disease Control and Prevention, and Health Resources and Services Administration) other Federal Departments (Defense, Veterans Affairs, State), and non-federal partners including academia, industry, professional medical and public health associations, states and localities, and the public. Dr. Salmon led a Secretary's initiative in vaccine safety, oversaw the 2009 H1N1 vaccine safety program, and served as the Designated Federal Official for the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group and the Advisory Commission on Childhood Vaccines (ACCV). Among other accomplishments, Dr. Salmon created the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Network to conduct active vaccine safety surveillance for the 2009 H1N1 immunization program. PRISM became an ongoing surveillance system for the Food and Drug Administration as a part of the Sentinel program.

Dr. Salmon has conducted a broad range of research in academia including research grants funded by the National Institutes of Health, Centers for Disease Control and Prevention, state health departments, the World Health Organization, Gavi, the Vaccine Alliance, the Robert Wood Johnson Foundation, and private industry including Walgreens, Pfizer, Merck and Crucell. Dr. Salmon has also served as a grant reviewer for the National Institutes for Health, Centers for Disease Control and Prevention, Food and Drug Administration, National Science Foundation, the Gates Foundation, as well as numerous other country federal health authorities. Dr. Salmon has taught and continues to teach a class in vaccine policy for two decades and also currently teaches a class in public health practice at Johns Hopkins University Bloomberg School of Public Health. Dr. Salmon has mentored numerous students and scientists, many of which now hold leadership positions in academia, government, and international organizations.

Dr. Salmon's research and practice work has included a broad range of studies examining the individual and community risks of vaccine refusal, the impact of laws and policies in increasing vaccination coverage and controlling vaccine preventable diseases, the reasons why patients and parents refuse vaccines, and the role of healthcare providers in impacting patient and parent vaccine decision-making. Dr. Salmon is widely considered a national and global expert in these areas. Dr. Salmon was a member of the Lancet Commission on Vaccine Hesitancy and served on a National Vaccine Advisory Committee Working Group on vaccine hesitancy.

Dr. Salmon has published more than 100 papers in top medical and public health journals including the New England Journal of Medicine, the Lancet, the Journal of the American Medical Association, Health Affairs, and Pediatrics. Dr. Salmon regularly serves as a peer reviewer for these and other high impact journals. He has been invited to give presentations at the National Foundation for Infectious Diseases, Federal advisory committees, and many international meetings. Dr. Salmon has served as an expert witness for a variety of legal cases. Dr. Salmon's current curriculum vitae is attached (Appendix 1).

Dr. Salmon has been retained by VIA Affiliates d/b/a Doylestown Health Physicians ("Doylestown Health"). Dr. Salmon has reviewed the following materials provided by Duane Morris LLP, on behalf of Doylestown Health:

1. Doylestown Health System Memorandum Re: COVID-19 Vaccination Mandate, August 6, 2021
2. COVID-19 Vaccines FAQ's transmitted on August 6, 2021 with Doylestown Health System Memorandum Re: COVID-19 Vaccination Mandate
3. Doylestown Hospital Occupational Health Services Immunization Policy, Review Date August 5, 2021
4. COVID-19 Vaccine Update, September 10, 2021
5. Doylestown Health Physicians (Medical Staff) COVID-19 Vaccine Mandate Announcement Email, August 6, 2021
6. Application for Religious Exemption For COVID-19 Vaccine
7. COVID Vaccination Documentation Requirement Email, August 13, 2021
8. COVID-19 Vaccine Requirement Email, August 30, 2021
9. Form of Letter Granting Exemption from COVID-19 Vaccination Mandate for Employees Remaining in Positions
10. Form of Letter Granting Exemption from COVID-19 Vaccination Mandate for Employees Reassigned to Different Positions
11. Managing DHS/Employees With COVID-19 Vaccine Exemption – Accommodation Strategies
12. List of Departments Reflecting Assessment of Patient Population Vulnerability for Each Department
13. Expert Report of Dr. Peter A. McCullough, MD, MPH

The client has not impacted the content of this report. All opinions herein are that of Dr. Salmon. Dr. Salmon has been compensated $20,000 for this report. Dr. Salmon will be

compensated at a rate of $450/hour for expert services rendered to Doylestown Health following completion of this expert report, including testimony at a deposition or trial.

Dr. Salmon was requested by the Defendant to provide opinions on the following issues:

Threats of COVID-19 to Patients and Healthcare Workers in November 2021

1. In November 2021, was COVID-19 a potentially fatal disease, particularly for vulnerable populations?

2. Are cardiac patients, particularly those undergoing cardiac surgery, more vulnerable to the threat of COVID-19 infection than other patients?

3. What are the risks of an unvaccinated person providing direct care, including surgery, to cardiac patients?

4. In November 2021, how did COVID-19 spread from person to person?

5. In November 2021, how did COVID-19 affect healthcare facilities, particularly with respect to patient access to care and quality of patient care?

6. In November 2021, what was the effect of asymptomatic transmission on the spread of COVID-19 on healthcare facilities?

7. In November 2021, how difficult was it for healthcare facilities to track the transmission of COVID-19 within the healthcare facility by vaccinated and/or unvaccinated persons, and would the data resulting from such tracking have been reliable?

8. Was exposure to COVID-19 an occupational hazard for employees of healthcare facilities?

9. Why were healthcare workers one of the first populations to receive the COVID-19 vaccine when it initially became available?

Safety and Efficacy of COVID-19 Vaccines

1. In November 2021, what was the efficacy of the available COVID-19 vaccines?

2. Does a COVID-19 vaccine that utilizes messenger ribonucleic acid (mRNA) have the effect of altering the genetic makeup of a person who receives such a vaccine?

3. Was the COVID-19 vaccine developed and manufactured by Janssen Biotech, Inc., an mRNA vaccine?

4. In November 2021, were unvaccinated persons, as compared to vaccinated persons, at an increased risk of becoming infected with COVID-19 and, therefore, transmitting the virus to others?

5. In November 2021, did available scientific evidence indicate that natural immunity (i.e., the presence of antibodies from prior infection) was as effective as vaccination to protect persons from COVID-19 infection?

6. In November 2021, was it possible to determine how long antibodies from prior COVID-19 infection could protect against subsequent COVID-19 infection?

7. In November 2021, did available scientific evidence indicate that antibodies from prior COVID-19 infection could protect persons against infection by a new strain of COVID-19?

Role of COVID-19 Vaccination Mandates in Managing Threats of COVID-19 to Patients and Healthcare Workers

1. In November 2021, did COVID-19 pose a direct threat to patients and healthcare workers?

2. In November 2021, were COVID-19 vaccination mandates a critical protection for patients and healthcare workers?

3. In November 2021, how effective were COVID-19 infection-control measures such as daily health questionnaires, temperature checks, and weekly testing, and were they sufficient safety measures in lieu of COVID-19 vaccination?

Effect of Non-Medical Exemptions From COVID-19 Vaccination Mandates

1. Did non-medical exemptions from COVID-19 vaccination mandates increase the risks of COVID-19 infection to patients and healthcare workers?

2. Did healthcare facilities have a responsibility to protect the safety of patients and staff by establishing and implementing processes for evaluating requests for exemption from COVID-19 vaccination mandates?

3. In evaluating requests for non-medical exemptions from COVID-19 vaccination mandates, was it appropriate to make distinctions between more vulnerable and less vulnerable patient populations for purposes of determining whether such a request could be accommodated?

Dr. Salmon's professional judgement in these areas is based upon review of current scientific evidence and federal advisory repots (referenced accordingly). However, at the request of counsel, data sources were limited to those available as of November 2021.

Threats of COVID-19 to Patients and Healthcare Workers in November 2021

In November 2021, was COVID-19 a potentially fatal disease, particularly for vulnerable populations?

COVID-19 was a very serious disease during this time as we were in the midst of a global pandemic with about 48 million cases of COVID-19 reported (November 15, 2021), about 35

million hospitalizations, and almost 760,000 deaths in the United States (U.S).[1] On November 15, 2021, the seven day average was about 95,000 cases, 48,000 hospitalizations, and 1,200 deaths. The CDC reported that 97% of hospitalizations and 99% of deaths were among unvaccinated persons in July, 2021.[2] Hospitalizations and deaths were disproportionately impacting the elderly and those with chronic medical conditions.[3] However, even some young and healthy individuals were experiencing serious disease, hospitalization and death. Vulnerable racial/ethnic populations (Black, Hispanic and Native American) were also disproportionately impacted by COVID-19.[4] The U.S. was experiencing the Delta (B.1.617.2) wave during this period. COVID-19 was appearing in waves and varied substantially by locality, state and region, as often is the case with infectious diseases.

Are cardiac patients, particularly those undergoing cardiac surgery, more vulnerable to the threat of COVID-19 infection than other patients?

It was well known in November 2021 that persons with cardiac disease were at increased risk for serious consequences from COVID-19. According to the American Heart Association in February, 2021: "Conditions such as heart failure (where the heart does not pump blood effectively), coronary artery disease (blocked arteries) and cardiomyopathies (weakening, thinning and/or thickening of the heart muscle) lead to more severe cases of COVID-19".[5] For these reasons, cardiac patients were particularly vulnerable to the health risks of COVID-19.

What are the risks of an unvaccinated person providing direct care, including surgery, to cardiac patients?

As discussed in greater detail below in connection with questions specifically about the risks of unvaccinated persons, an unvaccinated person was at increased risk of contracting and transmitting COVID-19 compared with a vaccinated person. Thus, an unvaccinated person providing direct care, including surgery, to cardiac patients was an increased risk to those cardiac patients compared to a vaccinated person providing direct care to cardiac patients. Given cardiac patients were among the high-risk groups for severe illness from COVID-19, the risk of unvaccinated persons providing care to this patient population was particularly high.

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[1] Johns Hopkins Coronavirus Resource Center. https://coronavirus.jhu.edu/region/united-states accessed 03/23/25.
[2] CNN interview with Dr. Walensky, CDC Director. https://www.cnn.com/2021/07/19/health/us-coronavirus-monday/index.html accessed 03/22/25.
[3] Centers for Disease Control and Prevention. People with Certain Medial Conditions. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html accessed 03/22/25.
[4] Don Bambino Geno Tai, Irene G. Sia, Chyke A. Doubeni, Mark L. Wieland. Disproportionate Impact of COVID-19 on Racial and Ethnic Minority Groups in the United States: a 2021 Update. J Racial Ethn Health Disparities. 2022; 9(6): 2334–2339.
[5] American Heart Association. https://www.heart.org/en/news/2021/02/11/heres-what-heart-patients-need-to-know-about-covid-19-in-2021 accessed 03/22/25.

In November 2021, how did COVID-19 spread from person to person?

It was well accepted among the scientific community at the time that COVID-19 spread person to person through respiratory droplets.[6] It was understood that the virus mainly spread between people in close contact with an infected person's mouth or nose when they cough, sneeze, speak, sing or breathe. This was particularly the case in indoor settings as aerosols could remain in the air. People could also be infected after touching surfaces or objects that had been contaminated with the virus.

In November 2021, how did COVID-19 affect healthcare facilities, particularly with respect to patient access to care and quality of patient care?

COVID-19 had a tremendous impact on healthcare systems, patient access to care and quality of care. As COVID-19 spread across the country in waves, disproportionately impacting some communities and then moving on to others, healthcare systems struggled to keep up with patient demand. Healthcare capacity in the United States is generally designed to meet demand, often with rural healthcare facilities below community needs. Consequently, the healthcare system was not well prepared for the surge of healthcare needs that resulted from COVID-19. The impact of COVID-19 on healthcare facilities was further strained by COVID-19 illness and death among healthcare workers and worker burnout.[7] Healthcare systems attempted to respond by establishing surge capacity, including portable morgues in hospitals for COVID-19 deaths. Additionally, healthcare providers and facilities delayed routine and non-emergency procedures to free up capacity to address heath care needs related to COVID-19.[8] The consequence was reduced access to care for patients and, in some cases, reductions in quality of care with increases in many diseases which were not diagnosed during routine care visits. The long-term impact of rationing healthcare because of the COVID-19 pandemic will take many years to fully characterize.

In November 2021, what was the effect of asymptomatic transmission on the spread of COVID-19 on healthcare facilities?

At this point, it was well accepted in the scientific community that asymptomatic persons were transmitting COVID-19.[9] Asymptomatic transmission of COVID-19 in healthcare facilities was a major problem through November 2021. Many healthcare facilities were regularly testing staff. However, such tests were imperfect and testing frequency limits the value of testing in detecting asymptomatic infections.[10]

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[6] Galbadage T, Peterson BM, Gunasekera RS. Does COVID-19 Spread Through Droplets Alone? Front Public Health. 2020 Apr 24;8:163.

[7] Wu H et al. National Healthcare Safety Network. Hospital capacities and shortages of healthcare resources among US hospitals during the coronavirus disease 2019 (COVID-19) pandemic, National Healthcare Safety Network (NHSN), March 27-July 14, 2020. Infect Control Hosp Epidemiol. 2022 Oct;43(10):1473-1476.

[8] The Rand Corporation. https://www.rand.org/content/dam/rand/pubs/research_briefs/RBA100/RBA164-1/RAND_RBA164-1.pdf accessed 03/22/24.

[9] Michael Johansson, Talia quandelacy, Sarah Kada et al. SARS-CoV-2 Transmission from People Without COVID-19 Symptoms. JAMA Netw Open. 2021;4(1):e2035057.

[10] Black JRM et al. COVID-19: the case for health-care worker screening to prevent hospital transmission. The Lancet. Volume 395, ISSUE 10234, P1418-1420, May 02, 2020.

In November 2021, how difficult was it for healthcare facilities to track the transmission of COVID-19 within the healthcare facility by vaccinated and/or unvaccinated persons, and would the data resulting from such tracking have been reliable?

It would be extremely difficult, labor intensive and costly for a healthcare facility to track the transmission of COVID-19 within a healthcare facility by vaccinated and/or unvaccinated persons. Additionally, doing so would require expertise not readily available to a healthcare facility, the data would be of poor quality, and it would take a lot of time further limiting the utility of such an endeavor as the virus would have likely mutated by the time the data were available.

For example, in July 2020 an article was published describing the investigation and management of a COVID-19 outbreak in Watford General Hospital, a 521-bed acute district general hospital situated in West Hertfordshire, U.K.[11] As described:

> SARS-CoV-2 outbreaks are difficult to recognise and control due to its high infectivity and the wide range of clinical manifestations of the infection…An outbreak control team (OCT) was convened…Root cause analyses (RCAs) were carried out on cases to identify possible causes, possible route of transmission and any learning points. All contact patients and staff were screened with RT PCR and genomic sequencing was performed on a set of positive specimens. In addition to active contact tracing, screening and cohorting of patients and staff, standard and transmission-based precautions were reinforced to control the outbreak…We recognised several challenges in investigating a COVID-19 outbreak in a hospital setting. Problems arising from variable sensitivity of the tests, difficulty in differentiating COVID-19 related symptoms from underlying diseases, problems related to establishing the route of transmission, issues with contact tracing.

If a healthcare facility were to track transmission, it would want to include identifying and implementing management processes so that there would be actionable information available to the healthcare facility. As described by the Centers for Medicare and Medicaid Services (CMS), root cause analysis is "a structured facilitated team process to identify root causes of an event that resulted in an undesired outcome and develop corrective actions. The RCA process provides you with a way to identify breakdowns in processes and systems that contributed to the event and how to prevent future events. The purpose of an RCA is to find out what happened, why it happened, and determine what changes need to be made."[12]

Once this entire process was complete, a hospital could then separate cases by vaccination status and try to ascertain chains of transmission (which would be very difficult and often inaccurate) to ascertain transmission by vaccination status. As a result, data from such tracking would not

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[11] Kannangara CI, Seetulsingh P, Foley J, Bennett G, Carter T. Investigation and management of an outbreak of COVID-19 infection in an acute admission unit in a District General Hospital: lessons learnt. Infect Prev Pract. 2021 Sep;3(3):100156.

[12] CMS. https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/guidanceforrca.pdf accessed 03/23/25.

be very reliable and therefore not actionable. Additionally, conducting this sort of analysis would be very labor intensive and costly, multi-disciplinary expertise to do so would be beyond many healthcare facilities and it would take a substantial amount of time to design the study and then collect, analyze and interpret the data. This sort of study would typically be conducted by academic researchers.

Was exposure to COVID-19 an occupational hazard for employees of healthcare facilities?

Specific to employees of healthcare facilities, the Occupational Safety and Health Administration (OSHA), Department of Labor, provides the following definition of healthcare workers: "Healthcare workers (HCWs) are occupationally exposed to a variety of infectious diseases during the performance of their duties. The delivery of healthcare services requires a broad range of workers, such as physicians, nurses, technicians, clinical laboratory workers, first responders, building maintenance, security and administrative personnel, social workers, food service, housekeeping, and mortuary personnel."[13] From an epidemiological perspective, some healthcare workers may be at greater risk than others based on their job duties, particularly those who come into more direct patient contact. However, to prevent nosocomial infections and protect patients and healthcare workers, hospitals and other healthcare facilities must take a system wide approach focusing on all persons who may acquire and transmit disease.

Healthcare workers were at risk of occupational acquired COVID-19 through exposure to infected patients and other healthcare staff. Particularly concerning would be healthcare workers at increased risk of COVID-19 morbidity and mortality. The Advisory Committee on Immunization Practices (ACIP) of the CDC consequently prioritized healthcare workers for vaccination.[14] More than 3,600 healthcare workers died of COVID-19 in the first year of the pandemic.[15] The prevalence of SARS-CoV-2 infection among healthcare workers was 11% in 2020, noticeably higher than in the general population.[16] In a large healthcare system of about 30,000 employees between June 1 to December 31, 2020, 2,357 employees were involved in occupational COVID-19 exposures; 1,128 (48%) were exposed to patients and 1,229 (52%) to other employees.[17]

Why were healthcare workers one of the first populations to receive the COVID-19 vaccine when it initially became available?

The Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) determined that healthcare personnel were the first priority for COVID-19 vaccine when it was available:

Phase 1a. Health care personnel (HCP) are being considered for phase 1a, which includes

[13] https://www.osha.gov/healthcare/infectious-diseases/ accessed 03/23/25.
[14] Bell BP, Romero JR , Lee GM. Scientific and ethical principles underlying recommendations from the advisory committee on immunization practices for COVID-19 vaccination implementation. *JAMA.* 2020; 324: 2025-2026
[15] KHN. 12 Months of Trauma: More Than 3,600 US Health Workers Died in Covid's First Year. https://khn.org/news/article/us-health-workers-deaths-covid-lost-on-the-frontline/ accessed 03/23/25.
[16] Sergio Alejandro Gómez-Ochoa et al. COVID-19 in Healthcare Workers: A Living Systematic Review and Meta-analysis of Prevalence, Risk Factors, Clinical Characteristics, and Outcomes. Am J Epidemiol. 2020 Sep 1.
[17] Jessica Ibiebele, Christina Silkaitis, Gina Dolgin et al. Occupational COVID-19 exposures and secondary cases among healthcare personnel. Am J Infect Control. 2021 Oct; 49(10): 1334–1336.

> the first available doses and an extremely constrained supply. HCP are defined as all paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials, comprising an estimated 20 million people. Examples include hospital, long-term care and assisted living, home health care, and outpatient facility staff, as well as pharmacies and emergency medical services. HCP are essential for the ongoing COVID-19 response and are at high risk for exposure to SARS-CoV-2.[18]

Healthcare personnel were the first priority for initial availability of COVID-19 vaccines for several reasons:

1) Healthcare personnel were at increased risk of contracting and transmitting COVID-19 because of their occupational exposure to COVID-19 cases;
2) Healthcare personnel were in regular contact with persons at increased risk of serious complications and death from COVID-19, including persons who were immunocompromised, had other comorbidities, and/or were elderly; and
3) Healthcare facilities were often at or beyond capacity caring for persons with COVID-19 as well as other healthcare needs. As essential personnel, reducing the risk of healthcare personnel contracting COVID-19 resulting in missed time from work and potentially morbidity and mortality was a local, state and national priority in order to maintain healthcare capacity; and
4) Given the sacrifice healthcare personnel were making to care for COVID-19 infected persons in addition to persons requiring other healthcare needs, it was equitable for personnel to receive all means available to protect themselves from COVID-19.

Safety and Efficacy of COVID-19 Vaccines

In November 2021, what was the efficacy of the available COVID-19 vaccines?

In November of 2021, three vaccines were available:
1) Moderna COVID-19 vaccine (mRNA-1273);
2) Pfizer and BioNTech COVID-19 vaccine (BNT162b2); and
3) Janssen Biotech COVID-19 vaccine (Ad26.COV2.S)

The most accurate estimates of the efficacy of COVID-19 vaccines at the time were based on the information available from the phase 3 clinical trials that were consider by the Food and Drug Administration (FDA) and its Vaccines and Related Biological Product Advisory Committee (VRBPAC), which were made available to the public.

The Moderna COVID-19 vaccine (mRNA-1273) was authorized for use to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Phase 3 randomized, double-blinded and placebo-controlled trial of mRNA-1273 included approximately 30,400 participants. The primary efficacy endpoint was the reduction of incidence of COVID-19 among participants without evidence of SARS-CoV-2 infection before the first dose of vaccine.

[18] Bell BP, Romero JR , Lee GM. Scientific and ethical principles underlying recommendations from the advisory committee on immunization practices for COVID-19 vaccination implementation. *JAMA.* 2020; 324: 2025-2026

Efficacy in preventing confirmed COVID-19 occurring at least 14 days after the second dose of vaccine was 94.5.0% (95% CI 86.5%, 97.8%). Subgroup analyses showed similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.[19]

The Pfizer and BioNTech COVID-19 vaccine (BNT162b2) was authorized for use to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Phase 3 randomized, double-blinded and placebo-controlled trial of BNT162b2 included approximately 44,000 participants. The primary efficacy endpoint was incidence of COVID-19 among participants without evidence of SARS-CoV-2 infection before or during the 2-dose vaccination regimen. Efficacy in preventing confirmed COVID-19 occurring at least 7 days after the second dose of vaccine was 95.0%. Subgroup analyses showed similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.[20]

Janssen Biotech COVID-19 vaccine (Ad26.COV2.S) was authorized for use to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Phase 3 randomized, double-blind and placebo-controlled trial of Ad26.COV2.S included approximately 40,000 participants. Vaccine efficacy against central laboratory-confirmed moderate to severe/critical COVID-19 was 66.9% (95% CI 59.0, 73.4) when considering cases occurring at least 14 days after the single-dose vaccination. Subgroup analyses showed similar efficacy across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19.[21]

The Delta variant was the most dominant strain in November 2021. It was widely accepted in the scientific community that the Delta variant had higher transmissibility and was responsible for the majority of illness, hospitalization and death in the US. Cases of COVID were reported among vaccinated persons (breakthrough cases) and there were indications that the vaccines were not as effective as previously characterized. The decrease in effectiveness may have been due to waning immunity of the vaccine (protection goes down over time) or because of differences in strain (Delta).

The most recent and highest quality data examining the effectiveness of vaccines, published by the CDC on August 27, 2021, was real world or observational data among frontline workers between December 14, 2020–August 14, 2021. [22]

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[19] Vaccines and Related Biological Products Advisory Committee Meeting. December 17, 2020. FDA Briefing Document. Moderna COVID-19 Vaccine. https://www.fda.gov/media/144434/download Accessed 03/23/2025.
[20] Vaccines and Related Biological Products Advisory Committee Meeting. December 10, 2020. FDA Briefing Document. Pfizer-BioNTech COVID-19 Vaccine. https://www.fda.gov/media/144245/download Accessed 03/23/2025.
[21] Vaccines and Related Biological Products Advisory Committee Meeting
February 26, 2021 FDA Briefing Document: Janssen Ad26.COV2.S Vaccine for the Prevention of COVID-19. https://www.fda.gov/media/146217/download. Accessed 03/23/2025.
[22] Centers for Disease Control and Prevention. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021. MMWR. August 27, 2021 / 70(34);1167-1169.

Regarding waning immunity, the CDC reported: "Adjusted VE against SARS-CoV-2 infection was 80% (95% confidence interval [CI] = 69%–88%). The VE point estimate was 85% among participants for whom <120 days had elapsed since completion of full vaccination compared with 73% among those for whom ≥150 days had elapsed; however the VE 95% CI were overlapping, indicating the difference was not statistically significant."

When focusing exclusively on the Delta variant, the CDC reported the following:

> During December 14, 2020–August 14, 2021, full vaccination with COVID-19 vaccines was 80% effective in preventing RT-PCR–confirmed SARS-CoV-2 infection among frontline workers, further affirming the highly protective benefit of full vaccination up to and through the most recent summer U.S. COVID-19 pandemic waves. The VE point estimates declined from 91% before predominance of the SARS-CoV-2 Delta variant to 66% since the SARS-CoV-2 Delta variant became predominant at the HEROES-RECOVER cohort study sites; however, this trend should be interpreted with caution because VE might also be declining as time since vaccination increases and because of poor precision in estimates due to limited number of weeks of observation and few infections among participants.

From these data and other similar limited and preliminary results in the scientific literature, it was clear that the vaccine was still very beneficial in preventing disease and consequent disease transmission. Concerns about waning immunity led to consideration of and ultimately recommendations for a booster doses.

Does a COVID-19 vaccine that utilizes messenger ribonucleic acid (mRNA) have the effect of altering the genetic makeup of a person who receives such a vaccine?

No, mRNA COVID-19 vaccines could not change someone's DNA (genetic makeup). As described by the National Human Genome Research Institute of the National Institute of Health at the time (August 30, 2021): "mRNA vaccines inject cells with instructions to generate a protein that is normally found on the surface of SARS-CoV-2, the virus that causes COVID-19…. mRNA vaccines are safe and cannot alter your DNA".[23] It was widely accepted among the scientific community that mRNA vaccines could not alter DNA.

Was the COVID-19 vaccine developed and manufactured by Janssen Biotech, Inc., an mRNA vaccine?

No, Janssen Biotech COVID-19 vaccine was not an mRNA vaccine. The Janssen vaccine was a viral (adenovirus) vector vaccine. Other viral vector vaccines include Japanese encephalitis, Lassa fever, Ebola, hepatitis B, hepatitis E and malaria.

In November 2021, were unvaccinated persons, as compared to vaccinated persons, at an increased risk of becoming infected with COVID-19 and, therefore, transmitting the virus to others?

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[23] National Human Genome Research Institute of the National Institute of Health. https://www.genome.gov/about-genomics/fact-sheets/Understanding-COVID-19-mRNA-Vaccines accessed 03/23/25.

Given the benefits of COVID-19 vaccines in reducing disease acquisition and transmission, unvaccinated persons were at an increased risk of contracting COVID-19 and transmitting it to others, including through meeting in person with fellow employees and patients, who could not be vaccinated because of medical contraindications as well as persons who were vaccinated but the vaccine did not sufficiently work for them (the vaccines were not 100% effective, see earlier discussion). The protection afforded by COVID-19 vaccines, like all vaccines, is not perfect so it was known that a vaccinated person could transmit disease. However, because the vaccines reduced the likelihood of infection, they also reduced the likelihood of transmission of disease to others. It was difficult to perfectly predict the reduced likelihood of disease transmission in vaccinated versus unvaccinated persons, particularly during a pandemic with evolving knowledge of the disease and uncertainty around mutations. Additionally, because experience with the vaccine was limited the potential for protection from the vaccine to wane over time was not well understood. Despite these limitations, it was widely accepted in the scientific community that COVID-19 vaccines reduced the likelihood of disease transmission and consequently unvaccinated persons were at increased risk of disease transmission.

In November 2021, did available scientific evidence indicate that natural immunity (i.e., the presence of antibodies from prior infection) was as effective as vaccination to protect persons from COVID-19 infection?

Several studies were available at that time that indicated an immune response to COVID-19 that lasted for at least a short time,[24, 25,26] reduced the risk of reinfection, [27] and infections provided some level of protection among Rhesus monkeys.[28] However, good correlates of protection were not available. A correlate of protection is a set of "empirically defined, quantifiable immune parameters that determine the attainment of protection against a given pathogen."[29] In other words, it was not known what sort or type of immune response or how strong an immune response was necessary to protect from COVID-19, including but not limited to new variants that might emerge. So, although it was measured that natural infection resulted in an immune response which lasted at least for months, it was not known if that immune response protected against COVID-19. Additionally, while there was some indication that infection reduced the risk of reinfection, there was not a good measure of how much it reduced reinfection nor for how long. A CDC study available in August of 2021 indicated that among previously infected persons, reinfection was about twice as high if not being fully vaccinated, leading CDC to recommend "To reduce their likelihood for future infection, all eligible persons should be

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[24] Staines HM, Kirwan DE, Clark DJ, et al. IgG seroconversion and pathophysiology in severe acute respiratory syndrome coronavirus 2 infection. Emerg Infect Dis. 2021 Jan;27.
[25] Wajnberg A, Amanat F, Firpo A, et al. Robust neutralizing antibodies to SARS-CoV-2 infection persist for months. Science. 2020 Dec;370(6521):1227-1230.
[26] Dan JM, Mateus J, Kato Y, et al. Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Science. 2021 Feb 5;371(6529):eabf4063.
[27] Gallais F, Gantner P, Bruel T, et al. Anti-SARS-CoV-2 Antibodies Persist for up to 13 Months and Reduce Risk of Reinfection. medRxiv. 2021.
[28] Bao L, Deng W, Gao H, et al. Lack of Reinfection in Rhesus Macaques Infected with SARS-CoV-2. bioRxiv. 2020.
[29] Altmann DM, Douek DC, Boyton RJ. What policy makers need to know about COVID-19 protective immunity. The Lancet. 2020 May;395(10236):1527–1529.

offered COVID-19 vaccine, even those with previous SARS-CoV-2 infection."[30] Natural immunity also comes with the potential for morbidity and mortality from COVID-19. Monitoring of healthy individuals for more than 35 years had shown that reinfection with the same seasonal coronavirus occurred frequently[31] and protection from seasonal coronavirus infections are short lived.[32]

In November 2021, was it possible to determine how long antibodies from prior COVID-19 infection could protect against subsequent COVID-19 infection?

In November 2021 there was not scientific consensus on how long prior COVID-19 infection would protect against subsequent COVID-19 infection.

In November 2021, did available scientific evidence indicate that antibodies from prior COVID-19 infection could protect persons against infection by a new strain of COVID-19?

In November 2021, available scientific evidence could not predict if antibodies from prior COVID-19 infection would protect against infection by a new strain of COVID-19. The virus was mutating in unpredictable ways domestically and globally. Scientists were struggling to keep track of these mutations and determining which mutation would become dominant. Additionally, not knowing what the new strain would be it was impossible to ascertain if prior infection from a previous infection would protect against a new strain.

Role of COVID-19 Vaccination Mandates in Managing Threats of COVID-19 to Patients and Healthcare Workers

In November 2021, did COVID-19 pose a direct threat to patients and healthcare workers?

In November 2021, COVID-19 posed a direct threat to patients and staff in healthcare facilities. Healthcare facilities around the country and the world were being overwhelmed by COVID-19. Healthcare staff were disproportionately impacted by COVID-19. Additionally, patients in healthcare facilities were at substantial risk of exposure to and infection with COVID-19 despite precautionary measures that were taken to reduce the risk of transmission in healthcare settings. Often, patients in healthcare settings were at increased risk of severe COVID-19 because of underlying health conditions and age.

In November 2021, were COVID-19 vaccination mandates a critical protection for patients and healthcare workers?

Mandatory COVID-19 vaccination policies for healthcare employees were a critical protective action at this time to protect patients and staff. As discussed, COVID-19 posed a direct threat to

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[30] Centers for Disease Control and Prevention. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. MMWR. August 13, 2021 / 70(32);1081-1083.
[31] Om E, Byrne P, Walsh KA, et al. Immune response following infection with SARS-CoV-2 and other coronaviruses: A rapid review. Rev Med Virol. 2021 Mar;31(2):e2162.
[32] Edridge AWD, Kaczorowska J, Hoste ACR, et al. Seasonal coronavirus protective immunity is short-lasting. Nat Med. 2020 Nov;26(11):1691–1693.

patients and staff in healthcare settings. Healthcare facilities around the country and the world were being overwhelmed by COVID-19. Healthcare staff were disproportionately impacted by COVID-19. Additionally, patients were at substantial risk of exposure and infection with COVID-19 despite precautionary measures that were taken to reduce the risk of transmission.[33]
Mandatory COVID-19 vaccine policies were a critical protective action to protect patients and staff for the following reasons:

1) COVID-19 posed a substantial threat to patients and staff;
2) COVID-19 vaccines provided a high level of protection against contracting COVID-19 and reducing transmission of COVID-19; and
3) Mandatory vaccination policies for influenza vaccines in healthcare settings have been demonstrated to be necessary to achieve high levels of vaccine coverage (voluntary policies even coupled with free access to vaccines and education did not achieve very high levels of vaccine coverage).

Mandatory COVID-19 vaccine policies were directly related to and often drew from mandatory influenza vaccine policies that have long been very important for healthcare institutions. Mandatory influenza vaccine policies are very important for healthcare institutions and directly relate to mandatory COVID-19 vaccine policies. Exposure to influenza in healthcare settings is an occupational hazard. Asymptomatic and healthcare workers who come to work ill (including the day before symptoms become apparent and the person is infectious) can transmit influenza to patients. Likewise, patients may be asymptomatic and transmitting influenza, including to unvaccinated healthcare workers and other patients. There is a broad range of strategies to reduce the risk of influenza among healthcare workers and protect patients who come into contact with such personnel. Strategies to reduce the risk of influenza in healthcare institutions include offering education and free, on-site vaccination, implementation of hand and respiratory hygiene and cough etiquette, screening and isolation of healthcare workers and patients with acute respiratory infections, and other prevention measures.[34]

Influenza vaccination is the most effective strategy to protect healthcare workers from contracting influenza and transmitting it to their patients. Vaccination of healthcare workers has been shown to be very effective, with minimal adverse effects, and shown to reduce patient mortality. [35] Despite considerable efforts at the Federal level and among states, with strong support from medical associations, influenza vaccination coverage among healthcare workers remains suboptimal.

Many healthcare institutions require influenza vaccination among their workers to protect their employees and the patients they care for. The Society for Healthcare Epidemiology of America (SHEA) strongly endorses mandatory vaccination of healthcare workers to protect against influenza, as can be seen in their most recent policy position on this topic:

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[33] Du Q et al. Nosocomial infection of COVID-19: A new challenge for healthcare professionals (Review). Int J Mol Med. 2021 Apr;47(4):31. doi: 10.3892/ijmm.2021.4864. Epub 2021 Feb 4.
[34] CDC. Prevention Strategies for Seasonal Influenza in Healthcare Settings. [cited 2011 17 November]; Available from: http://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm. accessed 03/23/25.
[35] Burls A, Jordan R, Barton P et al. Vaccinating healthcare workers against influenza to protect the vulnerable – is it. A good use of healthcare resources? A systematic review of the evidence and an economic evaluation. Vaccine. 2006. May 8; 24(19): 4212-21.

> SHEA views influenza vaccination of HCP as a *core patient and HCP safety practice* with which noncompliance should not be tolerated. It is the professional and ethical responsibility of HCP and the institutions within which they work to prevent the spread of infectious pathogens to their patients through evidence-based infection prevention practices, including influenza vaccination. *Therefore, for the safety of both patients and HCP, SHEA endorses a policy in which annual influenza vaccination is a condition of both initial and continued HCP employment and/or professional privileges.*[36]

Many professional medical and public health associations also support mandatory influenza vaccination of healthcare workers, including the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, the American Hospital Association, the American Medical Directors Association, the American Nurses Association, the American Public Health Association, the Association for Professionals in Infection Control and Epidemiology, the Infectious Disease Society of America, the National Association of County and City Health Officials, National Patient Safety Foundation, and others.[37]

This experience with influenza vaccine mandates in healthcare settings is directly applicable to COVID-19 mandates in healthcare settings. As with influenza, COVID-19 exposure in healthcare settings is an occupational hazard. Asymptomatic healthcare workers who come to work ill (including the day before symptoms become apparent and the person is infectious) can transmit COVID-19 to patients. Likewise, patients may be asymptomatic and transmitting COVID-19, including to unvaccinated healthcare workers and other patients. Voluntary programs for COVID-19 vaccination even coupled with access and education, as is the case with influenza, were unlikely to adequately reach very high levels of vaccine coverage necessary for protecting healthcare workers and patients. For example, we conducted a survey in late 2020 before the vaccines were available at SUNY Upstate Medical University in Syracuse, NY, the only academic medical center in Central New York and the region's largest employer with 9,565 employees.[38] We found that 57.5% of individuals expressed intent to receive COVID-19 vaccine, including 80.4% of physicians and scientists. Nearly half or more of nurses, Master's level clinicians, allied health professionals, and ancillary service personnel were not sure whether the vaccine would work and protect them from COVID-19; slightly lower but similar levels of uncertainty were expressed by the same groups about vaccine safety, and nearly a third of each group was unsure whether they would take a vaccine for COVID-19 if offered for free. The attitudes and concerns of nurses were very similar to those of the general public at the time. We conducted a follow-up survey in this healthcare system between 21 February and 19 March 2021 and found that 87.7% of respondents had already received a COVID-19 vaccine or planned to get vaccinated.[39] Physicians and scientists

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[36] Revised SHEA position paper: influenza vaccination of healthcare personnel. Infection Control and Hospital Epidemiology. Oct 2010. 31(10); 987-995.

[37] See https://www.immunize.org/honor-roll/influenza-mandates/ for list of these organizations that have policy positions supporting mandatory influenza vaccination for healthcare workers, including links to these policy statements. Accessed 03/23/25.

[38] Jana Shaw, Telisa Steward, Kathryn Anderson, Samantha Hanley, Stephen Thomas, Daniel Salmon, Christopher Morley. Assessment of U.S. health care personnel (HCP) attitudes towards COVID-19 vaccination in a large university health care system. Clin Infect Dis. 2021 Jan 25.

[39] Jana Shaw, Samantha Hanley, Telisa Steward, Daniel Salmon, Christin Ortiz, Paula Trief, Elizabeth Reddy, Christopher Morley, Stephen Thomas, Kathryn Anderson. Healthcare Personnel (HCP) Attitudes About

showed the highest acceptance rate (97.3%), whereas staff in ancillary services showed the lowest acceptance rate (79.9%). These levels of COVID-19 vaccine coverage were too low to provide adequate protection, leading New York to require vaccination of healthcare workers in September of 2021 and experiencing a 10% increase in vaccine coverage within a week.[40]

Similarly, many healthcare systems and medical providers were finding voluntary programs for COVID-19 vaccination to be insufficient and were thus turning to mandatory programs. According to the COVID States Project, as of July 2021, 27% of healthcare workers were unvaccinated and 15% were vaccine resistant, leading the authors to conclude that "absent mandates, most of the currently unvaccinated healthcare workers will remain unvaccinated, potentially fueling outbreaks in health care facilities."[41] A joint statement by 88 major medical organizations and associations called for mandatory vaccination of healthcare workers, including the American Hospital Association, the American Medical Association, the American College of Physicians, the American Academy of Family Physicians, and the American Public Health Association.[41,42] In August, 2021, the Department of Veterans Affairs announced that all employees and staff at VA facilities had to be vaccinated for COVID-19.[43] On September 9, 2021, President Biden announced a requirement for all healthcare workers working in settings that receive Medicare or Medicaid reimbursement to receive COVID-19 vaccines.[44]

In November 2021, how effective were COVID-19 infection-control measures such as daily health questionnaires, temperature checks, and weekly testing, and were they sufficient safety measures in lieu of COVID-19 vaccination?

Daily health questionnaires, temperature checks and weekly testing were not sufficient safety measures in lieu of vaccination. Health questionnaires are self-reported data, which are notoriously inaccurate. However, even if the person completing the questionnaire is perfectly accurate in their responses, as is largely the case with temperature checks (not self-reported), at best these approaches might be an indication that a test was warranted. However, by November of 2021, it had been well established that people could transmit COVID-19 before becoming symptomatic and among asymptomatic cases.

Regular testing for COVID-19 may allow for the identification of persons who have active disease. However, there are limitations to this approach. First, available COVID-19 tests are

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Coronavirus Disease 2019 (COVID-19) Vaccination After Emergency Use Authorization. Clin Infect Dis. 2022 Aug 24;75(1):e814-e821.

[40] Forbes. Covid-19 Vaccine Mandates Are Working—Here's The Proof https://www.forbes.com/sites/tommybeer/2021/10/04/covid-19-vaccine-mandates-are-working-heres-the-proof/?sh=8555e4b23058 accessed 03/23/25.

[41] Lazer David, et al. The COVID States Project #62: COVID-19 vaccine attitudes among healthcare workers. The COVID States Project. Aug 18, 2021

[42] Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care. https://assets.acponline.org/acp_policy/statements/joint_statement_covid_vaccine_mandate_2021.pdf accessed 03/23/25.

[43] US Department of Veteran Affairs. VA mandates COVID-19 vaccines among its medical employees including VHA facilities staff. https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5696 accessed 03/23/25.

[44] The White House. Remarks by President Biden on Fighting the COVID-19 Pandemic https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ accessed 03/23/25.

imperfect with the potential for both false positives and false negatives. Second, weekly COVID-19 testing would not identify people as soon as they became infectious, potentially allowing someone to transmit COVID-19 for up to a week before testing positive. Even daily testing would still miss cases transmitting disease between tests. Regardless of testing interval, in the time between when a person first became infectious and when the test was taken there was risk that the person would infect others.

Effect of Non-Medical Exemptions From COVID-19 Vaccination Mandates

Did non-medical exemptions from COVID-19 vaccination mandates increase the risks of COVID-19 infection to patients and healthcare workers?

Unvaccinated persons (those with medical and non-medical exemptions) are at increased risk of contracting disease and transmitting disease to unvaccinated individuals (including, but not limited to, others who cannot be vaccinated because of medical contraindications or who are too young to be vaccinated), and to vaccinated individuals for whom the vaccine did not work (no vaccine is 100% effective). The impact of non-medical exemptions has been extensively studied among children for pertussis and measles, though the epidemiological principles apply to influenza vaccine and non-medical exemptions among healthcare workers. Children who have non-medical exemptions are 22-35 times more likely to contract measles and 6 times more likely to contract pertussis than vaccinated children.[45,46] In addition to this individual risk, exempt persons also increase the risk to others. Studies we have conducted demonstrate that communities with higher rates of non-medical exemptions are at increased risk of pertussis outbreaks.[45,46,47] We also found that states that had easier non-medical exemptions processes for granting exemptions had higher rates of non-medical exemptions and higher rates of pertussis.[48,49]

Measles also highlights the community risks of vaccine refusal.[50] Measles has been eliminated in the United States because of sustained high coverage of a very safe and effective vaccine. However, there are communities in the United States with high rates of vaccine refusal and measles is still circulating in many parts of the world. As a result, measles is introduced into these communities with high rates of vaccine refusal – clustered socially or geographically –

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[45] Salmon DA, Haber M, Gangarosa EJ, Phillips L, Smith N, Chen RT. Health consequences of religious and philosophical exemptions from immunization laws: individual and societal risks of measles. JAMA. 1999 July 7; 282(1): 47-53.

[46] Feikin DR, Lezotte DC, Hamman RF, Salmon DA, Chen RT, Hoffman RE. Individual and community risks of measles and pertussis associated with personal exemptions to immunizations. JAMA. 2000 Dec. 27; 284(24): 3145-3150.

[47] Atwell JE, Van Otterloo J, Zipprich J, Winter K, Harriman K, Salmon DA, Halsey NA, Omer SB. Nonmedical vaccine exemptions and pertussis in California, 2010. Pediatrics. 2013 Oct;132(4):624-30.

[48] Rota JS, Salmon DA, Rodewald LE, Chen RT, Hibbs BF, Gangarosa EJ. Processes for obtaining nonmedical exemptions to state immunization laws. AJPH. April 2000; 91: 645-8.

[49] Omer SB, Pan WK, Halsey NA, Stokely S, Moulton LH, Navar AM, Salmon DA. Nonmedical Exemptions to School Immunization Requirements: Secular Trends and Association of State Policies with Pertussis Incidence. JAMA. 2006 Oct 11; 296(14):1757-63.

[50] Salmon DA, Dudley MZ*, Glanz JM, Omer SB. Vaccine hesitancy: Causes, consequences, and a call to action. Co-Published. Vaccine & Am J Prev Med. 2015 Nov 23; Suppl 4:D66-71.

resulting in outbreaks of measles.[51] An outbreak originating in Disneyland in 2015 caught the most national attention though there have been similar outbreaks in the Somali community in Minnesota and orthodox Jewish community in New York. As a result, the United States almost lost its "elimination status" in 2009, the same year that the World Health Organization declared vaccine hesitancy a top 10 global health threat. Several states (California, New York, Maine and Washington) have consequently eliminated their non-medical exemptions (Washington only eliminated non-medical exemptions for the MMR vaccine). There was recently a case of paralytic polio in the same orthodox Jewish community in New York which had the measles outbreak. This single case of polio indicates there are likely thousands of cases of asymptomatic polio in the community given the often-asymptomatic nature of polio. Sewage samples testing positive for polio support this.

These studies have been focused on children because every state has laws requiring vaccination for school entry. These studies have focused on measles and pertussis because the epidemiology of the diseases makes them well suited for such studies. However, the findings from these studies are very generalizable to non-medical exemptions to COVID-19 vaccine requirements for healthcare workers given the nature of infectious diseases and the impact of unvaccinated persons with exemptions. In fact, the impact of exemptions for COVID-19 vaccine among healthcare workers would be much higher than in the case with childhood vaccines because healthcare workers regularly come into contact with patients who are at increased risk for COVID-19 complications and death.

Did healthcare facilities have a responsibility to protect the safety of patients and staff by establishing and implementing processes for evaluating requests for exemption from COVID-19 vaccination mandates?

Exemptions to COVID-19 vaccine requirements had the potential to undermine vaccine requirements, particularly if a large number of exemptions were granted. However, many COVID-19 vaccine requirements were implemented in such a way that exemptions were either not granted or only a small number of exemptions were granted, and in such situations, there were substantial increases in vaccine coverage and a small number of persons who left employment because of the mandates. Many healthcare institutions that instituted mandates offered medical exemptions for those with valid medical contraindications and religious exemptions. Even if medical exemptions met guidelines for contraindications or religious exemptions were determined to be sincere, many healthcare institutions determined that the risks to others imposed an undue burden and, consequently, did not grant some or all exemption requests.

As previously described, each non-medical exemption a healthcare facility granted increased the risk of COVID-19 disease transmission and outbreaks adversely impacting other healthcare staff, patients, and the capacity of the healthcare system to operate. One can reasonably conclude that exemptions would be geographically clustered, increasing their impact, given COVID-19 vaccine hesitancy had been shown to geographically cluster and healthcare workers tended to live in the communities in which they work.

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[51] Phadke VK. Bednarczyk RA, Salmon DA, Omer SB. Association between Vaccine Refusal and Vaccine Preventable Diseases in the United States: A Focus on Measles and Pertussis. JAMA. 2016 Mar; 315(11): 1149-58.

In evaluating requests for non-medical exemptions from COVID-19 vaccination mandates, was it appropriate to make distinctions between more vulnerable and less vulnerable patient populations for purposes of determining whether such a request could be accommodated?

It was appropriate, based upon available scientific evidence, to make distinctions between more vulnerable and less vulnerable patients for the purpose of evaluating exemption requests. As described, unvaccinated (exempt) staff were at increased risk of contracting and transmitting COVID-19 compared with vaccinated staff. The increased risk of unvaccinated (exempt) staff compared to vaccinated staff included the risk of transmission to other staff and patients. Many patients in this setting were at increased risk of severe disease, while other patients were not at increased risk of severe disease. Of particular concern was the increased risk of unvaccinated (exempt) staff to patients at increased risk of severe disease. At this time, subpopulations at increased risk of severe disease (such as those with cardiac disease) were well characterized. Requiring unvaccinated (exempt) staff to only work with less-vulnerable patients was based upon well accepted science at the time and could be expected to reduce or mitigate the risk of unvaccinated (exempt) staff.

Conclusion

In summary, in November 2021 the world was amid a global pandemic with the United States experiencing a large number of cases and substantial morbidity and mortality. Certain subpopulations such as the elderly and persons with underlying health conditions, such as cardiac patients, were at substantial increased risk of more severe disease and death if they contracted COVID-19. Healthcare institutions were particularly hard hit by COVID-19, experiencing high rates of disease and struggling to meet patient needs given limited capacity. Unvaccinated healthcare workers were at increased risk of contracting and transmitting COVID-19.

At the time, it was well accepted in the scientific and medical communities that COVID-19 was spread from person to person and people could asymptomatically transmit disease. It would have been extremely difficult for a healthcare facility to track transmission by vaccination status and any such efforts would not have yielded reliable and actionable information.

COVID-19 was an occupational hazard and, for all the foregoing reasons, healthcare workers were prioritized by the CDC to be among the first to receive the vaccine. Three vaccines were available at the time, and they were found to be very safe and effective. While there was indication that there was some level of natural immunity post infection, it was unclear how effective and for how long natural infection would provide protection and there was no evidence to indicate how well natural infection would protect against the next variant. Because of the risk of COVID-19 transmission from unvaccinated healthcare workers to high-risk patients and suboptimal voluntary vaccine acceptance among healthcare workers, and following the model of influenza vaccine, many healthcare institutions implemented mandatory COVID-19 vaccination polices.

Measures such as daily health questionnaires, temperature checks and weekly testing were insufficient in leu of vaccination. Non-medical exemptions to COVID-19 vaccine requirements increased the risk of COVID-19 to patients and healthcare workers. Healthcare facilities had a responsibility to protect the safety of patients and staff by evaluating exemption requests. It was very reasonable and consistent with available science to make a distinction between staff who interacted with more vulnerable versus less vulnerable patients for the purpose of evaluating exemption requests.

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Global Disease Epidemiology and Control
Department of International Health
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Education and Training

2003 PhD, Health Policy and Management, Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD
Dissertation: *School Implementation of Immunization Requirements: Are School Policies or Personnel Associated with the Likelihood of a Child Claiming an Exemptions or School-Based Outbreaks of Measles or Pertussis?*

1996 MPH, Health Policy and Management, Emory University Rollins School of Public Health, Atlanta, GA
Thesis: *Health Consequences of Religious and Philosophical Exemptions from Immunization Laws: Individual and Societal Risk of Measles*

1991 BA, Political Science with Minor in Psychology, Rutgers University, New Brunswick, NJ

Professional Experience

2018 - Director, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health

2017 - Professor, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health

2017 - Professor, Health, Behavior and Society (joint appointment), The Johns Hopkins University, Bloomberg School of Public Health

2018 - 2021 Director of PhD Program, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health

2012 - 2018	Deputy Director, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
2012 - 2017	Associate Professor, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health
2013 - 2017	Associate Professor, Health, Behavior and Society (joint appointment), The Johns Hopkins University, Bloomberg School of Public Health
2007 - 2012	Director of Vaccine Safety (GS 15 – Step 10), National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services
2007 - 2012	Adjunct Associate Professor, Global Disease Epidemiology and Control, Department of International Health, The Johns Hopkins University, Bloomberg School of Public Health
2005 - 2007	Associate Professor, Department of Epidemiology and Health Policy Research, University of Florida, College of Medicine
2003 - 2005	Assistant Scientist, Division of Disease Prevention and Control, Department of International Health, Associate Director for Policy and Behavioral Research, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
2001 - 2003	Research Associate, Division of Disease Prevention and Control, Department of International Health, Associate Director for Policy and Behavioral Research, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
1999 - 2001	Consultant, Institute for Vaccine Safety, The Johns Hopkins University, Bloomberg School of Public Health
2000	Consultant, Merck Vaccine Division, Merck and Co, Inc.
1997 - 1999	Policy Analyst, National Vaccine Program Office, Centers for Disease Control and Prevention
1995 -1997	Contractor, National Immunization Program, Centers for Disease Control and Prevention
1994 - 1995	HIV Prevention Community Coordinator, Health Visions, Inc.
1994	Consultant, Health Visions, Inc.

1990 - 1992 Residential Aide/Counselor, Alternatives, Inc.

Professional Activities

Society Membership

- American Public Health Association, Member (1995-1999)
- Infectious Disease Society of America, Member (2005-2007)

Advisory Panels

Advisory Panels

- National Academy of Science, Engineering, and Medicine. Guidance on Routine Childhood Immunization (2004)
- National Vaccine Advisory Committee (NVAC) Vaccine Confidence Working Group (2020-2022)
- Moderna Vaccine Safety Board (2020-2022)
- Merck Vaccine Confidence Board (2019, 2023)
- 39th National Immunization Conference External Planning Committee (2004)
- Merck Vaccine Policy Board Member (2007)
- Parents of Kids with Infectious Diseases (PKIDS), Board Member (2007- 2010)
- Brighton Collaboration, Board Member, Vaccine Hesitancy Working Group Co-Chair (2012-2020)
- National Vaccine Advisory Committee (NVAC) Vaccine Confidence Working Group (2018-22)
- Janssen Vaccine Policy Board Member (2021)
- Moderna Vaccine Safety Board (2022-2023)

Editorial Activities

Peer Reviewer (selected)

- American Journal of Preventive Medicine
- American Journal of Public Health
- Archives of Pediatric and Adolescent Medicine
- Biosecurity and Bioterrorism
- BMC Family Practice
- BMC Public Health
- Expert Reviews of Vaccines
- Health Affairs
- Health Education Research
- Indian Journal of Medical Science
- Journal of Comparative Family Studies
- Journal of Health Communication
- Journal of the American Medical Association
- Journal of the National Medical Association
- Journal of Urban Health

- New England Journal of Medicine
- Pediatrics Pediatric Infectious Disease Journal
- Pediatrics International
- Public Health Reports
- The Lancet
- The Lancet Infectious Diseases
- Vaccine
- Vaccines

Editorial Board
Vaccine, Associate Editor (2021- 2022)
Vaccines (2012-2013)

Guest Editor
Pediatrics Supplement: Vaccine Safety Throughout the Product Life Cycle (2011)
Vaccines Supplement: Confidence in Vaccines (2013)

Review of Proposals (selected)

Health Promotion in Communities (HPC) Study Section National Institutes of Health (standing member) and Dissemination & Implementation in Heath Study Section (DIHR, ad hoc reviewer). Special Emphasis Panels for National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration (Chair), National Science Foundation, and Canadian Institutes of Health Research.

Honors and Awards

- Haddon Fellow, Johns Hopkins University Bloomberg School of Public Health (1999-2001)
- Achievement Award – Dedication to Students, Johns Hopkins Bloomberg School of Public Health (2005)
- Development of the Federal Immunization Safety Task Force, Assistant Secretary for Health (2008)
- Federal Monitoring of H1N1 Vaccine Safety, Assistant Secretary for Health (2010)
- Patient Education Working Group Co-Chair, Assistant Secretary for Health (2012)
- Outstanding recent graduate (within past 10 years), Johns Hopkins Bloomberg School of Public Health (2013)
- Delta Omega Society (2014)

Publications **(* indicated student/advisee/mentee)**

Journal Articles (Peer Reviewed)

1. Powell TW, Forr A, Johnson S, Clinton T, Gaither J, Brewer J, Dudley MZ, Holifield J, Wilson P, Benson LR, Harr L, **Salmon DA**, Mendelson T. The Voices on Vax Campaign:

Lessons Learned from Engaging Youth to Promote COVID Vaccination. Prog Community Health Partnersh. 2024;18(3):345-353.

2. Kitano T, Dudley MZ, Engineer L, Thompson DA, **Salmon DA**. The authors reply to Kurita et al and Lataster. Am J Epidemiol. 2024 Jun 3;193(6):932-934.
3. Salmon DA, Orenstein WA, Plotkin SA, Chen RT. Funding Postauthorization Vaccine-Safety Science. N Engl J Med. 2024 Jul 11;391(2):102-105. doi: 10.1056/NEJMp2402379. Epub 2024 Jul 6.
4. Zapf AJ, Schuh HB, Dudley MZ, Rimal RN, Harvey SA, Shaw J, Balgobin K, **Salmon DA**. Knowledge, attitudes, and intentions regarding COVID-19 vaccination in the general population and the effect of different framing messages for a brief video on intentions to get vaccinated among unvaccinated individuals in the United States during July 2021. Patient Educ Couns. 2024 Jul;124:108258.
5. Dudley MZ, Schuh HB, Forr A, Shaw J, **Salmon DA**. Changes in vaccine attitudes and recommendations among US Healthcare Personnel during the COVID-19 pandemic. NPJ Vaccines. 2024 Feb 28;9(1):49.
6. **Salmon DA**, Chen RT, Black S, Sharfstein J. Lessons learned from COVID-19, H1N1, and routine vaccine pharmacovigilance in the United States: a path to a more robust vaccine safety program. Expert Opin Drug Saf. 2024 Feb;23(2):161-175.
7. Kitano T, **Salmon DA**, Dudley MZ, Thompson DA, Engineer L. Benefit-Risk Assessment of mRNA COVID-19 Vaccines in Children Aged 6 Months to 4 Years in the Omicron Era. J Pediatric Infect Dis Soc. 2024 Feb 26;13(2):129-135.
8. Dudley MZ, Schuh HB, Goryn M, Shaw J, **Salmon DA**. Attitudes toward COVID-19 and Other Vaccines: Comparing Parents to Other Adults, September 2022. Vaccines (Basel). 2023 Nov 21;11(12):1735.
9. Dudley MZ, Schwartz B, Brewer J, Kan L, Bernier R, Gerber JE, Budigan Ni H*, Proveaux TM, Rimal RN, **Salmon DA**. COVID-19 vaccination attitudes, values, intentions: US parents for their children, September 2021. Vaccine. 2023 Nov 30;41(49):7395-7408.
10. Delamater PL, Buttenheim AM, **Salmon DA**, Schwartz JL, Omer SB. Kindergarten Vaccination Status in California After Changes to Medical Exemption Policy. JAMA. 2023 Oct 24;330(16):1585-1587.
11. Schuh HB, Rimal RN, Breiman RF, Orton PZ, Dudley MZ, Kao LS, Sargent RH, Laurie S, Weakland LF, Lavery JV, Orenstein WA, Brewer J, Jamison AM*, Shaw J, Josiah Willock R, Gust DA, **Salmon DA**. Evaluation of online videos to engage viewers and support decision-making for COVID-19 vaccination: how narratives and race/ethnicity enhance viewer experiences. Front Public Health. 2023 Aug 21;11:1192676.
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Commentaries

1. **Salmon DA**, Black S, Didierlaurent AM, Moulton LH. Commentary on "Common Vaccines and the Risk of Dementia: A Population-Based Cohort Study": Science Can be Messy but Eventually Leads to Truths. J Infect Dis. 2023 May 29;227(11):1224-1226.
2. Gostin LO, Shaw J, **Salmon DA.** Mandatory SARS-CoV-2 Vaccinations in K-12 Schools, Colleges/Universities, and Businesses. JAMA. 2021 Jun 7. *Invited*
3. Gostin LO, **Salmon DA**, Larson HJ. Mandating COVID-19 Vaccines. JAMA. 2021 Feb 9;325(6):532-533. doi: 10.1001/jama.2020.26553. PMID: 33372955. *Invited*
4. Opel DJ, **Salmon DA**, Marcuse EK. Building Trust to Achieve Confidence in COVID-19 Vaccines. JAMA Netw Open. 2020 Oct 1;3(10):e2025672. doi: *Invited*
5. **Salmon DA**, Dudley MZ, Carleton BC. Guillain-Barré Syndrome Following Influenza Vaccines Affords Opportunity to Improve Vaccine Confidence. J Infect Dis. 2021 Feb 13;223(3):355-358. doi: 10.1093/infdis/jiaa544. PMID: 33137189. *Invited*
6. **Salmon DA**, Dudley MZ. It is time to get serious about vaccine confidence. Lancet. 2020 Sep 26;396(10255):870-871. doi: 10.1016/S0140-6736(20)31603-2. Epub 2020 Sep 10. PMID: 32919522. *Invited*
7. Gostin LO, **Salmon DA**. The Dual Epidemics of COVID-19 and Influenza: Vaccine Acceptance, Coverage, and Mandates. JAMA. 2020 Jul 28;324(4):335-336. doi: 10.1001/jama.2020.10802. PMID: 32525519. *Invited*
8. **Salmon DA**, MacIntyre CR, Omer SB. Making mandatory vaccination truly compulsory: well intentioned but ill conceived. Lancet Infect Dis. 2015 Aug;15(8):872-3.
9. Halsey NA, **Salmon DA**. Measles at Disneyland, a problem for all ages. Ann Intern Med. 2015 May 5;162(9):655-6. *Invited*
10. Atwell JE*, **Salmon DA**. Pertussis resurgence and vaccine uptake: implications for reducing vaccine hesitancy. Pediatrics. 2014 Sep; 134(3): 602-4. *Invited*
11. **Salmon DA**, Halsey. Guillain-Barré Syndrome and vaccination. Clin Infect Dis. 2013 Jul; 57(2):205-7. *Invited*

12. **Salmon DA**, Halsey NA. Keeping the M in medical exemptions: protecting our most vulnerable children. J Infect Dis. 2012 Oct 1; 206(7): 987-8.
13. MacIntyre CR, Kelly H, Jolley D, Butzkueven H, **Salmon D**, Halsey N, Moulton LH Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. Neurology. 2005 Apr 12;64(7):1317.

Books

The Clinician's Vaccine Safety Resource Guide: Optimizing the Prevention of Vaccine-Preventable Diseases Across the Lifespan. Mathew Z. Dudley. **Daniel A Salmon**, Neal A. Halsey, alter A. Orenstein, Rupali J. Limaye, Sean T. O'Leary, Saad B. Omer. Springer Publishing, 2018.

Government and Advisory Committee Reports

1. White Paper on the United States Vaccine Safety System. National Vaccine Advisory Committee (NVAC), 2012. Role: Served as the Designated Federal Official for the Vaccine Safety Working Group with responsibilities including determining the charge and membership of the working group, holding closed and public meetings to gather scientific and programmatic information and incorporation of stakeholder views, and oversaw drafting of final report.
2. H1N1 Vaccine Safety Risk Assessment Working Group (VSRAWG). National Vaccine Advisory Committee (NVAC). Interim reports (12/2009, 1/2010, 2/2010, 3/2010, 4/2010, 6/2010) and final report (1/2012). Role: Served as the Designated Federal Official with responsibilities including determining the charge and membership of the VSRAWG, coordinating bi-monthly conference calls with the Federal Immunization Safety Task Force and the VSRAWG reviewing all H1N1 safety data, facilitated discussions of safety issues among the VSRAWG, drafting all reports.
3. Recommendations on 2009 H1N1 Influenza Vaccine Safety Monitoring. National Vaccine Advisory Committee (NVAC). 7/2009. Role: Served as the Designated Federal Official for the Vaccine Safety Working Group with responsibilities including determining the charge and membership of the Working Group, holding meetings with Working Group and HHS leadership, and drafting final report.
4. Federal Plans to Monitor Immunization Safety for Pandemic 2009 H1N1 Influenza Vaccination Program. Department of Health and Human Services, 2009. Role: Primary author with the Federal Immunization Safety Task Force.
5. Recommendations on the Centers for Disease Control and Prevention Immunization Safety Office Draft 5-Year Scientific Agenda. National Vaccine Advisory Committee (NVAC), 2009. Role: Served as the Designated Federal Official for the Vaccine Safety Working Group with responsibilities including determining the charge and membership of the working group, holding closed and public meetings to gather scientific and programmatic information and incorporation of stakeholder views, and oversaw drafting final report.
6. A Comprehensive Review of Federal Vaccine Safety Programs and Pubic Health Activities. Department of Health and Human Services, 2008. Role: Primary author with the Federal Immunization Safety Task Force.
7. Vaccine Safety Action Plan (Implementation Plan for the Task Force Report on Safer Childhood Vaccines). Department of Health and Human Services, 1999. Role: Primary author with the many HHS agencies (NIH, FDA, CDC, HRSA).

Practice Activities

Dr. Salmon's public health practice has been carried out while he held positions in the Federal government and academia and has resulted in 15 peer reviewed publications, 7 Federal and advisory committee reports, dozens of testimony to Federal advisory committees and state legislators, regular consultation with policy-makers, and more than 50 interviews with national media outlets. This practice work has been funded by state and Federal government agencies, has been integrated into Dr. Salmon's teaching, and has resulted in several awards for outstanding services by the Assistant Secretary for Health. Dr. Salmon's leadership has impacted policy and public health practice nationally. Dr. Salmon has assisted in the development of model state laws for school immunization requirements, based upon public health scholarship, and evaluated the impact of the application of this model. Dr. Salmon was a major contributor to realigning vaccine safety activities within the Centers for Disease Control and Prevention in order to provide greater public confidence in vaccine safety, surveillance and response activities.

While serving as the Director of Vaccine Safety at the National Vaccine Program Office, Dr. Salmon led an inter-agency and inter-departmental Secretarial task force, The Federal Immunization Safety Task Force, responsible for ensuring the coordination and strategic planning of Federal vaccine safety activities. Under his leadership, this Task Force wrote a Secretarial report to enhance our vaccine safety systems and the safety chapter of the National Vaccine Plan. Dr. Salmon led the development of the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group, issuing reports to the Assistant Secretary for Health to improve the national vaccine safety system and focus vaccine safety research activities. This Working Group was cited by RAND on how to effectively utilize the National Vaccine Advisory Committee. The Department of Health and Human Services has been able to garner and focus vaccine safety programmatic and research activities through these internal government and advisory committee reports.

The 2009-10 H1N1 vaccine program brought unusual challenges and opportunities for vaccine safety and Dr. Salmon's work. The last national effort to quickly vaccinate the country to prevent a novel swine flu pandemic in 1976 resulted in a public health and political failure as the vaccine caused Guillain-Barré syndrome (GBS) and the pandemic never materialized as anticipated. The New York Times referred to this as the Swine Flu Fiasco as the Director of the Centers for Disease Control and Prevention and the Surgeon General were dismissed as President Ford faced public criticism. A new administration and the public remembered this experience as the 2009-10 H1N1 vaccine program was launched with considerable skepticism. Dr. Salmon seized these challenges and was able to capitalize on them to ensure the safety monitoring was robust and credible and build long lasting infrastructure.

Dr. Salmon oversaw the largest and most comprehensive vaccine safety monitoring program (2009-10 H1N1 vaccine program) ever in the US or internationally. Dr. Salmon worked with seven agencies in the Department of Health and Human Services, as well as the Departments of Defense and Veterans Affairs, to enhance active safety monitoring programs. Dr. Salmon developed a novel vaccine safety surveillance system, the Post Licensure Rapid Immunization Safety Monitoring (PRISM) Network that is now a part of permanent infrastructure at the Food

and Drug Administration and has served as a model for drug and product safety monitoring. Dr. Salmon led the Federal Immunization Safety Task Force to develop a safety-monitoring plan for H1N1 that was shared with stakeholders and the public and once the program was launched. To enhance public and stakeholder engagement and improve public confidence, Dr. Salmon developed the H1N1 Vaccine Safety Risk Assessment Working Group of the National Vaccine Advisory Committee that provided independent oversight of all 2009-10 H1N1 vaccine data across the government every two weeks and provided publically deliberated reports on a monthly basis throughout the vaccine program. Dr. Salmon's work in this area was cited by an Institute of Medicine report reviewing the National Vaccine Plan and Federal vaccine activities as an area in vaccines with exemplary leadership and coordination. Many aspects of this 2009-10 H1N1 vaccine program that were instituted under his leadership continue today.

Testimony

Dr. Salmon has made dozens of presentations to the National Vaccine Advisory Committee (NVAC), Advisory Commission on Childhood Vaccines (ACCV), the Advisory Committee on Immunization Practices (ACIP), and the National Biodefense Science Board (NBSB). He has also provided testimony for the Maryland and Florida Legislators.

Expert Testimony in Legal Cases (past 5 years)

1. *Mitra v Mullenax,*
   Court of Common Pleas, Crawford County, PA, Case No. F.D. 2022-35
   Testimony at trial

2. *Connolly v. Biomarin Pharmaceuticals Inc..*
   USDC, Southern District of Texas, Case No. 4:23-cv-00938
   Testimony at arbitration hearing

3. *Marcoux, et al v. Eisenhower Medical Center*
   Riverside County, CA Superior Court, Case No. CVPS2203384
   Deposition

Presentations to Policy-Makers

Dr. Salmon has provided dozens of briefings for 3 CDC Directors, 3 Secretary's, two Deputy Secretary's, and 5 Assistant Secretary's for Health, U.S Department of Health and Human Services.

Consultations with Policy-Makers and Other Stakeholders

Served as the Federal Ex-Officio for the Advisory Commission on Childhood Vaccines (ACCV; 2007-2012) which provides advice to the Secretary, HHS, regarding the Vaccine Injury Compensation Program (HRSA). Developed working groups (as the Designated Federal Official) of the National Vaccine Advisory Committee (NVAC) that provides policy advice to the Director of the National Vaccine Program/Assistant Secretary for Health to optimize the prevention of disease through vaccination and the prevention of vaccine adverse events.

Through Dr. Salmon's leadership, the NVAC produced the following reports: 1) Review and prioritization of CDC Immunization Safety Office research agenda; 2) Recommendations for improving the Nations vaccine safety system; 3) Recommendations for improvements to H1N1 safety monitoring programs; and 4) Independent ongoing review of all H1N1 safety data. Through these Federal Advisory Committee efforts, Dr. Salmon worked closely with a very broad range of stakeholders including state and local health departments, Federal agencies (NIH, FDA, CDC, HRSA, IHS) and departments (HHS, DoD, VA, USAID), vaccine manufacturers, professional associations, academia, and advocacy organizations. Dr. Salmon has held many local, regional and national meetings to engage these stakeholders in vaccine policy and practice, issuing meeting reports, and impacting the policy and practice recommendation of the aforementioned advisory committee reports.

Research Finding Dissemination through Media Appearances

Dr. Salmon has made many media appearances and contributed to stories for CNN, Reuters News, The Associated Press, The New York Times, The Wall Street Journal, The Washington Post, The LA Times, and many other city, state and national media outlets.

Software Development

Developing and evaluating immunization App to increase maternal and infant vaccination uptake.

Practice Positions (outside academia)

Director of Vaccine Safety, National Vaccine Program Office, Office of the Assistant Secretary for Health, US Department of Health and Human Services (2007-2012): Coordinated, evaluated and provided leadership for federal vaccine safety programs.

- Developed a Secretarial Task Force (Federal Immunization Safety Task Force) issuing a report to the Secretary to enhance safety systems and providing ongoing coordination and leadership of Federal vaccine safety activities.
- Coordinated Federal H1N1 vaccine safety monitoring across multiple HHS Agencies and Departments, including development of federal strategic planning, addressing emerging issues, and development of innovative initiatives.
- Developed a novel active surveillance system (Post Licensure Rapid Immunization Safety Monitoring (PRISM)) for H1N1 vaccination program, capturing vaccine histories from 8 state immunization registries linked with health records for about 35 million persons through 5 large health insurance companies. This program is now a permanent part of vaccine safety monitoring by the FDA.
- Conducted a meta-analysis combining GBS data across multiple safety monitoring systems and worked with Vaccine Injury Compensation Program (HRSA) to determine if GBS should be a compensatable injury.
- Guest Edited supplement for Pediatrics to improve understanding of vaccine safety systems and science and enable effective communications by pediatricians when discussing vaccine safety with parents.

CURRICULUM VITAE

Daniel Salmon
Part II

Teaching

Masters Advisees

- Ann Marie Navar, 2005
- Jana Goins, 2005
- Bernadette Cambell, 2005
- Brian Rosen, 2013
- Kevin Wright, 2013
- Benjamin Williams, 2013
- Matthew Dudley, 2013
- Bansari Patel, 2013
- Oladeji Oloko, 2014
- Hannah Steinberg, 2014
- Moar Sherbini, 2014
- Aderemi Sanusi, 2016
- Caroline Picher, 2016
- Nicholas Albaugh, 2019
- Alex Zapf, 2020
- Emily Clifford, 2021
- Alexandria Cull Weatherer, 2021
- Alex Paulenich, 2022
- Azim Abdul Wahid, 2023
- Amar Fadeel, 2023
- Ana Stevens, 2024
- Gabby Liu (23/25 cohort)
- Angela Zhai (24/26 cohort)

Doctoral Advisees

- Dustin Gibson, PhD, 2014
- Matthew Dudley, PhD, 2019
- Andrea Carcelen, PhD, 2020
- Jennifer Gerber, PhD, 2020
- Taylor Halroyd, PhD, 2020

Preliminary Oral Participation

- Saad Omer, 2004
- Dustin Gibson, 2012

- Elizabeth Chmielewski, 2016

Final Oral Participation

- Saad Omer, 2006: "Societal Risk of Pertussis in the United States: Role of State Policies and Spatial Clustering of Childhood Vaccine Refusers"
- Ann Marie Navar, 2009: "Impact of Immunization in the Neonatal Intensive Care Unit"
- Zunera Gilani (alternate), 2012: "Population Immunity to Measles and Rubella Virus in Rural Zambia"
- Noor Rakshani, DRPH, 2013: "Individual and Contextual Level Factors Influencing Initiation, Completion and Up to Date Vaccination in Routine Immunization Program"
- Jennifer Kreslake (chair), 2014: "Determinants of Risk Behaviors in the Containment of Highly Pathogenic Avian Influenza and Implications for Risk Communication"
- Dustin Gibson, 2014: "The Readiness, Need for, and Effect of mHealth Interventions to Improve Immunization Timeliness and Coverage in Rural Western Kenya"
- Brittany Kmush, 2016: "Determinants of Immunologic Persistence of Hepatitis E Virus Antibodies." (alternate)

MSPH/Post-MPH Internships Hired and Supervised (Current position, number of co-authored papers)

- Ann Marie Navar, 2006 (Associate Professor of Medicine (Cardiology)
- UT Southwestern Medical School; 5 papers)
- Terrel Carter, 2007 (American Academy of Pediatrics, Global Immunization Staff; 4 papers)
- Stephanie Irving, 2007 (Kaiser Permanente Center for Health Research; 1 paper)
- Kirsten Vannice, 2008-10 (World Health Organization & Gates; 6 papers)
- Michelle Mergler, 2009-10 (Johns Hopkins Doctoral Student; 2 papers)
- Will Bleser, 2010 (Duke Policy Center; 3 paper)

Classroom Instruction

Primary Instructor

2003 - Vaccine Policy Issues (223.687.01). This 3-credit course examines current national and international policy issues in vaccine research, development, manufacturing, supply, and utilization. Topics include development of orphan vaccines, ensuring an adequate supply of safe and effective vaccines, vaccine injury compensation, and disease eradication. Emphasizes the identification of important vaccine policy issues and the development and evaluation of policies to address these issues. Presents the roles, responsibilities, and policy positions of key immunization stakeholders via guest lectures by a wide array of experts who have worked for important vaccine groups (i.e., FDA, GAVI, Vaccine Industry, US Vaccine Injury Compensation Program, Consumer Group). 35-45 students masters and doctoral students from across the School of Public Health and

Preventive Medicine Residents. Consistently received high student course evaluations.

2018 - The Practice of Public Health Through Vaccine Case Studies: Problem Solving Seminar (223.630.81). Vaccines are among the most effective medical and public health interventions. This class for DrPH students presents historic vaccine case studies highlighting challenges in emerging science, program design and evaluation, management, policy and communication. The seminar examines decision-making surrounded by scientific uncertainty, controversy and competing public health priorities and explores the challenges of developing policy and practice decisions within the constraints of emerging and uncertain science. Students are challenged to make policy decisions and develop programmatic and communication strategies in real world settings.

2012 - 2013 Vaccine Policy Issues (223.687.98). Johns Hopkins Fall Institute, Barcelona, Spain.

Co-Instructor

2004-05 Public Health Practice (305.607.01). This 4 credit course focused on the areas of knowledge and skills necessary to the administration of health agencies. The course covered topics such as administrative structure, intergovernmental relations, legislation, politics, and the public budgetary process with reference to health departments on the federal, state, and local levels. The course also reviewed public sector issues for which health agencies are responsible, including AIDS, health promotion strategies, primary care, and immunization programs. Developed and taught class on-site and online.

Research Grant Participation

Adult Immunization Quality Improvement for Providers (IQIP)
Sponsor: CDC
Role: Principal Investigator (15% effort)
Dates: 08/01/23 – 08/01/26
Project: Develop, evaluate and widely disseminate an evidence-based QI program for immunization that integrates adult-specific strategies across healthcare provider settings.

Evaluating Social Media as a Tool for Connecting Vulnerable Communities with a Personalized Vaccination Decision-Making Website
Sponsor: Vaccine Confidence Fund
Role: Principal Investigator (15% effort)
Dates: 04/01/23 – 03/01/24
Project: Evaluate the relative impact and cost effectiveness of grassroot public health efforts vs. paid social media strategies on community engagement with LetsTalkShots.

LetsTalkCOVIDVaccines | Orange County, New York
Sponsor: Orange County Health Department
Role: Principal Investigator (20% effort)

Dates: 12/01/22 – 12/01/23
Project: Pilot the LetsTalkShots provider talking points with Little Pediatrics in Orange County, NY.

Improving Vaccine Acceptance through EHR Integrated Patient- and Provider-Facing Decision Support
Sponsor: Merck Sharp And Dohme Corp
Role: Principal Investigator (10% effort)
Dates: 11/01/22 – 11/01/24,
Project: Establish the technical feasibility and evaluate the effectiveness of a scalable, integrated platform to improve patient informed decision-making and increase vaccine uptake.

Health Care Provider Training to Increase Vaccine Uptake and Reduce Vaccine Hesitancy
Sponsor: Merck Sharp And Dohme Corp
Role: Principal Investigator (15% effort)
Dates: 01/11/2021 – 01/10/2025
Project: Develop and evaluate Johns Hopkins CME module teaching how clinicians can effectively communicate with patients about vaccines and conversion of Springer published clinical guide into Unbound Medicine version.

Public and Health Care Provider knowledge, attitudes, beliefs, intentions, and behaviors regarding COVID-19 disease and SARS-CoV-2 vaccines: the mediating role of trust in health care providers and public health authorities
Sponsor: Merck Sharp And Dohme Corp
Role: Principal Investigator (10% effort)
Dates: 01/11/2021 – 01/11/2024
Project: Evaluate the immediate impact of outbreaks of COVID-19 disease and response measures on uptake of recommended vaccines, including but not limited to SARS-CoV-2 vaccines (when such vaccines are recommended), with a focus on trust in health care providers and public health authorities, and their vaccine knowledge, attitudes
and beliefs.

TweenVax: A comprehensive practice-, provider-, and parent/patient-level intervention to improve adolescent HPV vaccination
Sponsoring Agency: National Cancer Institute, National Institutes of Health
Role: Co-Investigator (5% effort)
Dates: 09/01/2019 – 06/30/2024
Project: The aim of the project is to develop and refine the practice-, provider-, and patient/parent-level intervention that will be tested in primary care pediatric and family practice offices for adolescents aged 9-14.

LetsTalkCovidVaccine Tailored for Local Communities
Sponsor: NACCHO
Role: Principal Investigator (20% effort)
Dates: 12/1/2021 - 7/31/2023
Project: Tailored LetsTalkCovidVaccine, a personalized health communication tool, to five underserved communities.

Assessing Vaccine Hesitancy and a Pharmacist Led Intervention Model to
Sponsor: XULA
Role: Co- Investigator (5% effort)
Dates: 11/13/2020 - 5/23/2023
Project: Training pharmacists to work with vaccine hesitant patients.

LetsTalkCovidVaccine Tailored for Guilford County
Sponsor: GCGPH
Role: Principal Investigator (5% effort)
Dates: 3/1/2022 - 10/31/2022
Project: Tailored LetsTalkCovidVaccine, a personalized health communication tool, to Guildford County, NC.

CGHI Vaccine Access and Training (VAT) Initiative for a Community-Based Workforce
Sponsor: GHC3
Role: Co-Investigator (20% effort)
Dates: 3/1/2022 - 10/31/2022
Project: Trained over 100 community health workers to go into their vulnerable communities and work with vaccine hesitant persons.

Vaccine Hesitancy for COVID 19
Sponsor: NACHC
Role: Principal Investigator (20% effort)
Dates: 7/15/2021 - 6/30/2022
Project: Built LetsTalkCovidVacciens, a personalized risk communication tool, based on our MomsTalkShots model.

Let's talk COVID shots web app for Canadians
Sponsor: CPHA
Role: Principal Investigator (10% effort)
Dates: 10/1/2021 - 3/18/2022
Project: Tailored LetsTalkCovidVaccine, a personalized health communication tool, for Canada.

SARS-CoV2 Vaccines Information Equity and Demand Creation Project (COVIED)
Sponsor: Centers for Disease Control and Prevention
Role: Multiple Principal Investigator (mPIs Robert Breiman and Walter Orenstein) (25% effort)
Dates: 02/01/2021-09/31/2021
Project: Implements a systematic approach to provide interpretable, context- and culture-specific accurate and trusted information about the vaccines that will be offered, and to package and deliver this information to susceptible populations at risk for COVID and demonstrating vaccine hesitancy as a means to substantively reduce the disproportionate impact of COVID illness and death associated with this pandemic.

Understanding Diverse Communities and Supporting Equitable and Informed COVID-19 Vaccination Decision-Making
Sponsor: Robert Wood Johnson Foundation

Role: Principal Investigator (20% effort)
Dates: 11/1/2020-9/1/2021
Project: Collaborat with NACCH, ASTHO, AIM and NIHB to better understand how people are approaching decision-making regarding COVID-19 vaccination and what additional information they need to make an informed decision for themselves, their family, and their community.

Valuation of Vaccine Safety
Sponsor: GAVI
Role: Principal Investigator (20% effort)
Dates: 07/15/2020 – 07/31/2021
Project: Quantify the health and economic costs associated with the vaccine safety disaster that occurred in the Ukraine in 2008 where there was a decline in vaccine public confidence triggered by mishandled death following a measles vaccine campaign, leading to a large measles outbreak including exportation to other countries.

Impact of Eliminating Non-Medical Exemptions in California
Sponsoring Agency: National Institute of Allergy and Infectious Diseases, National Institutes of Health
Role: Co-Investigator (20% effort)
Dates: 2016-2021
Project: California is the first state in decades to abolish non-medical exemptions to school immunization requirements. This study examines the implementation and impact of this change by assessing the burdens on health care providers, health departments, schools and parents and the rates of medical exemptions and home schooling.

PHASE II: Development and Writing of the Global Vaccine Safety Blueprint 2.0
Sponsor: WHO
Role: Principal Investigator (15% effort)
Dates: 1/17/2020 - 4/30/2020
Project: In collaboration with the World Health Organization, drafted verson 2.0 of the Global Vaccine Safey Blueprint.

Ethical, Legal and Social Issues (ELSI) for Precision Medicine and Infectious Disease: Centers for Excellence in ELSI Research (CEER)
Sponsoring Agency: National Human Genome Research Institute, National Institutes of Health
Role: Co-Investigator, Lead Vaccinomics (15% effort)
Dates: 2016-2020
Project: Anticipate and examine the ethical, legal, social, historical and policy issues confronting the incorporation of genomics in the prevention, outbreak control, and treatment of a range of infectious diseases, and plan for the responsible translation of genomic advances into practice.

A Comprehensive Pre-natal Intervention to Increase Vaccine Coverage
Sponsoring Agency: National Institutes of Health: Dissemination and Implementation Research in Health (R01)
Role: Multiple Principal Investigator (with Saad Omer, Emory University) (35% effort)
Dates: 2015-2020
Project: Develop and evaluate a comprehensive intervention at the patient, provider and practice

levels to increase maternal and childhood vaccine uptake.

Cocooning (influenza and Tdap vaccines)
Sponsor: Walgreens
Role: Principal Investigator (15% effort)
Dates: 1/26/2017 - 6/30/2019
Project: Randomized controlled Trial to ascertain the impact of MomsTalkShots on friends and family of pregnant women.

The Vaccine Safety Communication E-Library
Sponsor: WHO
Role: Principal Investigator (5% effort)
Dates: 02/01/2019 – 04/30/2019
Project: The objective is to work with the WHO vaccine safety office to develop the e-library by assisting with growing the content and enhancing the organization and searchability of the VSN e-library and the development of a plan of action to increase participation of members and new members.

Programmatic Impact of Multi-dose Vaccines
Sponsoring Agency: Bill and Melinda Gates Institute through the Johns Snow Institute
Role: Co-Investigator (10% effort)
Dates: 2016-2018
Project: Equip global and country level decision makers with the evidence, guidance, and tools needed to assess when, where, and how the selection of vaccine presentation affects timely, equitable, and safe vaccination coverage.

Case Studies of the Impact of Meningitis Epidemics on Local Health Departments and College Health Facilities
Sponsoring Agency: Pfizer
Role: Principal Investigator (25% effort)
Dates: 2015-2016
Project: Evaluate the non-medical costs associated with Meningitis outbreaks in university settings.

Capitalizing on Recent Changes to School Immunization Requirements to Improve the Publics Health
Sponsoring Agency: Robert Wood Johnson Foundation Public Health Law Program
Role: Hopkins Principal Investigator (10% effort)
Dates: 2014-2016
Project: Evaluate the implementation and impact of recent changes made to state school immunization requirements and develop model school immunization law.

Note: Dr. Salmon was a Federal employee for 5 years and consequently could not receive external funding

Evaluation of Parents Claiming Exemptions to School Entry Immunization Requirements

Sponsoring Agency: Centers for Disease Control and Prevention
Role: Principal Investigator (20% effort)
Dates: 2004-2006
Project: Examine the secular trends and geographical clustering of immunization exemptions and associations with pertussis, reasons why parents refuse vaccines, and conducted a content analysis of vaccine safety newspaper stories.

Mentored Patient-Oriented Research Career Development Award (K23). Decision Making of Parents to Vaccinate Their Children
Sponsoring Agency: National Institutes of Health
Role: Principal Investigator (75% effort)
Dates: 2004-2007
Project: Explore the role of health care providers in influencing parental vaccination decisions.

Policy and Ethical Consultation on Pandemic Planning and Public Health Emergencies
Sponsoring Agency: Florida Department of Health
Role: Principal Investigator (10% effort)
Dates: 2005-2006
Project: Explore ethical issues regarding responding to an influenza pandemic and developed a training module for public health workers to understand ethical issues surrounding vaccination during a pandemic.

Implementation of Mandatory Immunization Requirements
Sponsoring Agency: Centers for Disease Control and Prevention
Role: Co-Principal Investigator (with Neal Halsey) (75% effort)
Dates: 2001-2003
Project: Assess the role of school personnel and school policies in implementing immunization requirements. Explored the reasons why some parents claim exemptions to school immunization requirements.

The Role of School Personnel and Policies in Implementing Immunization Requirements
Sponsoring Agency: Washington State Department of Health
Role: Principal Investigator (10% effort)
Dates: 2001-2004
Project: Explore the role of school personnel and school policies in implementing immunization requirements in Washington State.

Academic Service

2003 - 2005	Admissions Committee for MSPH Program, Disease Prevention and Control, Department of International Health, Johns Hopkins Bloomberg School of Public Health
2005 - 2007	Epidemiology Program Director, Interdisciplinary Program (IDP), University of Florida, College of Medicine
2012 -	Admissions Committee for PhD Program, Global Disease Epidemiology and Control, Department of International Health, Johns Hopkins Bloomberg School of Public Health

2014 - Honors and Awards Committee, Department of International Health, Johns Hopkins Bloomberg School of Public Health
2015 - Public Health Practice Committee, Johns Hopkins Bloomberg School of Health

Advisory Committee Presentations (selected)

2020 National Vaccine Advisory Committee, Vaccine Confidence Working Group
2006 National Vaccine Advisory Committee, Adolescent Vaccine Working Group. *History and Impact of School Immunization Requirements: Implications for Adolescent Vaccination*
2004 National Vaccine Advisory Committee, Subcommittee on Vaccine Safety. *Enhancing Public Confidence in Vaccines through Independent Oversight of Post-Licensure Vaccine Safety*
2002 National Vaccine Advisory Committee Working Group on Implementing Vaccine Recommendations, *presentation to the Committee and expert witness for panel discussion*
1998 National Vaccine Advisory Committee Working Group on Philosophical Exemptions, *presentation to the Committee*

Personal Statement

Dr. Salmon's primary research and practice interest is optimizing the prevention of childhood infectious diseases through the use of vaccines. He is broadly trained in vaccinology, with an emphasis in epidemiology, behavioral epidemiology, and health policy. Dr. Salmon's focus has been on determining the individual and community risks of vaccine refusal, understanding factors that impact vaccine acceptance, evaluating and improving state laws providing exemptions to school immunization requirements, developing systems and science in vaccine safety, and effective vaccine risk communication. Dr. Salmon has considerable experience developing surveillance systems, using surveillance data for epidemiological studies, and measuring immunization coverage through a variety of approaches. Dr. Salmon has worked with state and federal public health agencies to strengthen immunization programs and pandemic planning.

Controversies have always existed around vaccines. However, increasingly parents are worried about the safety of vaccines and the rates of parents refusing vaccines have been increasing. Dr. Salmon's led the first study quantifying the individual and community risks of measles associated with vaccine refusal. He and others have replicated these studies examining the risk of vaccine refusers for pertussis, *Haemophilus influenzae* type b, varicella, and pneumococcal. Dr. Salmon's studies in this area have demonstrated that local clustering of refusal is associated with measles and pertussis, explaining why we see sporadic measles outbreaks despite very high vaccine coverage nationally. Dr. Salmon's work quantifying the individual and community risks of disease resulting from vaccine refusal has directly impacted national and state policy in this area.

Having quantified the magnitude of the problem of vaccine refusal, Dr. Salmon conducted a broad range of studies examining factors that contribute to vaccine acceptance and refusal. He conducted studies comparing parents who refused vaccines for their children compared to parents of fully vaccinated children. He then linked these parents to their healthcare providers to understand the impact of healthcare providers on parental vaccine decision-making. Dr. Salmon conducted studies exploring the impact of school-level personnel and policies on vaccine refusal and the impact of the media's focus on vaccine safety.

Dr. Salmon's investigations of parents who refuse vaccines for their children have included parents who claim exemptions to school immunization requirements because they are actively deciding to refuse vaccines altogether rather than delay vaccines. Dr. Salmon has investigated compulsory vaccination in the US compared to other developed countries. He has explored how school laws are implemented and enforced at the state and local level and how this impacts the rates of exemptions. He developed an evidence-based model state exemption law that has been implemented in various forms in many states to strengthen their state exemption laws. He has evaluated the impact of these applications of this model and is in the process of revising this model law with a broad range of stakeholders. Dr. Salmon's work in this area has largely shaped the debate we see in many states making exemption laws more stringent and offers a policy approach to limiting exemptions while preserving parental autonomy.

Concerns about the safety of vaccines are the primary (but not the only) reason that parents are increasingly refusing vaccines. Dr. Salmon has focused on developing the science base for vaccine safety. He served as the Director for Vaccine Safety, National Vaccine Program Office, HHS, where he was responsible for coordinating and leading our national vaccine safety efforts

including, but not limited to, the 2009 H1N1 vaccine program. In this capacity, Dr. Salmon improved our vaccine safety systems. During the H1N1 vaccine program he oversaw the largest, most comprehensive vaccine safety monitoring program ever in the US and the world. Dr. Salmon developed a new active surveillance system (Post-licensure Rapid Immunization Safety Monitoring (PRISM) Network) that is now a permanent part of our vaccine safety monitoring program. He created independent vaccine safety assessment to improve trust and confidence. The success of these efforts was highlighted by the IOM when reviewing the National Vaccine Plan. Dr. Salmon has also conducted safety studies, such as the most comprehensive evaluation of GBS post-influenza vaccine since 1976. Dr. Salmon is currently a board member of the Brighton Collaboration, an international network of vaccine safety investigators, and co-chairs their vaccine confidence working group.

While improving safety systems and science is essential to addressing parental safety concerns, it is necessary to effectively communicate the risks and benefits of vaccines to the scientific community, healthcare providers, the media and the public. To work toward this objective, Dr. Salmon has conducted vaccine risk perception and communication studies, developed communication strategies for the Department of Health and Human Services and its Agencies, and developed resources for healthcare providers. Dr. Salmon is currently focused on developing and evaluating interventions at the patient, provider and practice levels to improve maternal and infant vaccine acceptance. Dr. Salmon was the guest editor to a supplement in Pediatrics that assisted pediatricians in working with vaccine hesitant parents by reviewing the complex vaccine safety system in the US, reviewing factors that impact vaccine hesitancy, and assisting pediatricians with how to communicate with parents. Dr. Salmon is widely considered a national and international expert in vaccine safety and factors impacting vaccine acceptance.

Keywords

Vaccine, Immunization, Infectious Diseases, Epidemiology, Health Policy, Public Health Practice